

## **REMARKS**

### **I. Introduction**

With the addition of new claims 45 and 46, claims 11, 12, 15 to 20, 28, 31 to 33, 39, 40, 42 to 44, 45, and 46 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

### **II. Rejection of Claims 11, 12, 15 to 17, 28, 31 to 33, and 44 Under 35 U.S.C. § 102(b)**

Claims 11, 12, 15 to 17, 28, 31 to 33, and 44 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,176,127 (“Dormia”). It is respectfully submitted that Dormia does not anticipate these claims for at least the following reasons.

The Office Action reflects an apparent misapprehension of the disclosure of Dormia. In particular, the Office Action considers the configuration illustrated at Figure 6 to be the same device illustrated in Figure 8. Although Dormia may reuse certain reference numerals between Figures 6 and 8, Dormia makes abundantly clear that **the device illustrated in Figure 8 is a different device than the device illustrated in Figure 6**. See, e.g., col. 3, lines 21 to 34 and col. 5, lines 21 to 32. Thus, the assertion that a portion of the device of Figure 8 is “expanded against the tubular member as in Fig. 6” is not supported by the disclosure of Dormia. Indeed, Dormia does not provide any disclosure or suggestion whatsoever that either of portions 16 and 18 of the device in Figure 8 is in any manner capable of being arranged to reflect the features of the device illustrated in Figure 6; rather the structural features of the device of Figure 8 differ substantially with respect to the features of the device of Figure 6. Moreover, referring to Figure 8 of Dormia, relied upon by the Examiner for allegedly disclosing an annular groove, the head portion 12 does not appear to make any form of contact with the jacket 1, regardless of whether the head portion 12 is in the fully contracted position (as illustrated in the left half of Figure 8) or the fully expanded position (as illustrated in the right half of Figure 8).

Although Applicants do not necessarily agree with the merits of the present rejection, but to facilitate prosecution, each of claims 11, 28, 39, and 44 has been amended herein without prejudice to change “such that the distal end of the

tubular member contacts a side of the annular groove to constrain the proximal end of the distal portion against radial contraction” to --such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction--. Support for these amendments may be found, for example, at page10, lines 18 to 28.

Dormia relates to a mandrel for a medical endoscope and describe devices that include a mandrel head 9 that expands to extend over the end 3 of the jacket 1. See, e.g., col. 3, lines 58 to 63, col. 4, lines 3 to 50 and Figures 3 and 8. In this regard, the mandrel head 9 is held in the expanded state by using rod-shaped slide or mandrel 10, the mandrel head moving radially inwardly when the mandrel 10 is removed. Col. 4, lines 3 to 60 and Figures 6 and 8.

The Office Action contends that element 18 of the device of Figure 8 of Dormia constitutes an annular groove. The Office Action further contends that element 1 of Dormia constitutes a tubular member. However, no side of element 18 is contacted by element 1 in any manner that constrains a proximal end of the mandrel head 9, which the Office Action considers to constitute a distal portion, against radial contraction. Rather, as indicated above, any expansion and contraction of the mandrel head 9 is dictated by the insertion and removal of the mandrel 10. Thus, it is plainly apparent that Dormia does not disclose, or even suggest, a distal portion including a proximal end having an annular groove that receives the distal end of a tubular member **such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction**, as recited in claims 11 and 39, or the step of detachably securing a proximal end of a distal portion to a distal end of a tubular member by receiving the distal end of the tubular member in an annular groove at the proximal end of the distal portion **such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction**, as recited in claim 28. Dormia also does not disclose, or even suggest, a distal portion having a proximal end having an annular groove configured to receive the distal end of the tubular member **such that contact between the distal end of the tubular member and a side of the annular groove constrains the proximal end of the distal portion against radial contraction**, as recited in claim 44.

As indicated above, Dormia does not disclose, or even suggest, all of the features recited in any of claims 11, 28, and 39. As such, it is respectfully submitted that Dormia does not anticipate any of claims 11, 28, and 39, or any claim that depends from any of claims 11, 28, and 39. Accordingly, withdrawal of this rejection is respectfully requested.

**III. Rejection of Claims 11 to 16, 19, and 39 to 44 Under 35 U.S.C. § 102(b)**

Claims 11 to 16, 19, and 39 to 44 were rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 6,332,877 ("Michels"). It is respectfully submitted that Michels does not anticipate these claims for at least the following reasons.

The Examiner contends at pages 4 to 5 of the Office Action that Michels discloses a an introducer having a distal portion having a proximal end that contracts after being released from a tubular member. To support this position, the Examiner points to column 5, line 14 of Michels, which indicates that, after being detached, the tip is dissolved. As best understood by Applicants, the Examiner considers a general disclosure of dissolution of an element to constitute a contraction and reduction in diameter of that element. However, Michels et al. does not disclose whether the dissolution of the tip involves any expansion, contraction, or any change whatsoever with respect to the diameter of the tip. Thus, the Examiner's contention that dissolution of an element includes a contraction and reduction of diameter of that element appears to be based on mere **speculation and conjecture**, which cannot support the present rejection. Further, to the extent that the Examiner may be relying on personal knowledge, Applicants request that the Examiner provide specific evidence under 37 C.F.R. § 1.104(d)(2) or otherwise (in particular, an affidavit or published information).

Although Applicants may not agree with the merits of this rejection, but to facilitate prosecution, claims 11, 39, and 44 have been amended herein without prejudice to recite that the proximal end of the distal portion is configured to **contract from a radially outward position to a radially inward position**. Support for these amendments may be found, for example, at page10, lines 18 to 28.

It is plainly apparent that the dissolution disclosed by Michels does not constitute a contraction from a radially outward position to a radially inward position. Indeed, Michels does not disclose, or even suggest, a proximal end of a distal

portion that is configured to contract from a radially outward position to a radially inward position, as recited in claims 11, 39, and 44.

As set forth above, Michels does not disclose, or even suggest, all of the features recited in any of claims 11, 39, and 44. As such, it is respectfully submitted that Michels does not anticipate any of claims 11, 39, and 44, or any claim that ultimately depends from any of claims 11, 39, and 44. Accordingly, withdrawal of this rejection is respectfully requested.

#### **IV. Rejection of Claims 20 and 39 to 43 Under 35 U.S.C. § 103(a)**

Claims 20 and 39 to 43 were rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Dormia and U.S. Patent No. 6,042,538 (“Puskas”). It is respectfully submitted that the combination of Dormia and Puskas does not render unpatentable these claims for at least the following reasons.

As an initial matter, claim 41 has been previously canceled. As such, the present rejection of claim 41 is moot.

Claim 20 depends from claim 11 and therefore includes all of the features of claim 11. As indicated above, Dormia does not disclose, or even suggest, all of the features of claim 11. Puskas is not relied upon for disclosing the features of claim 11 not disclosed or suggested by Dormia. Indeed, Puskas does not disclose, or even suggest, the features of claim 11 not disclosed or suggested by Dormia. As such, the combination of Dormia and Puskas et al. does not disclose, or even suggest, all of the features of claim 20. Accordingly, it is respectfully submitted that the combination of Dormia and Puskas does not render unpatentable claim 20.

As indicated above, Dormia does not disclose, or even suggest, all of the features of claim 39. Puskas is not relied upon for disclosing the features of claim 39 not disclosed or suggested by Dormia. Indeed, Puskas does not disclose, or even suggest, the features of claim 39 not disclosed or suggested by the by Dormia. As such, it is respectfully submitted that the combination of Dormia and Puskas does not render unpatentable claim 39 or any of claims 40, 42, and 43, which depend from claim 39.

In view of all of the foregoing, withdrawal of this rejection is respectfully requested.

**V. Rejection of Claims 18 and 19 Under 35 U.S.C. § 103(a)**

Claims 18 and 19 were rejected under 35 U.S.C. § 103(a) as unpatentable over Dormia. It is respectfully submitted that Dormia does not render unpatentable these claims for at least the following reasons.

Claims 18 and 19 ultimately depend from claim 11 and therefore include all of the features of claim 11. As set forth above, Dormia does not disclose, or even suggest, all of the features of claim 11. Accordingly, Dormia does not disclose, or even suggest, all of the features of either of claims 18 and 19. As such, Dormia does not render unpatentable either of claims 18 and 19. Withdrawal of this rejection is therefore respectfully requested.

**VI. New Claims 45 and 46**

New claims 45 and 46 have been added. It is respectfully submitted that new claims 45 and 46 add no new matter and are fully supported by the present application, including the Specification. Support may be found, for example, at page 10, lines 18 to 28 of the Specification.

Since claims 45 and 46 depend from claim 44 and therefore include all of the features of claim 44, it is respectfully submitted that claims 45 and 46 are patentable over the references relied upon for at least the same reasons set forth above in support of the patentability of claim 44.

**VII. Conclusion**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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